IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Saumil N. Merchant et al.
Serial No. : 09/625,644
Filed : July 26, 2000
Title : MIDDLE-EAR IMPLANT

Art Unit : 3738
Examiner : D. Isabella

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

RELATED APPEALS AND INTERFERENCES

The Examiner states that the appeal brief contains no statement of related appeals and interferences. Applicant draws attention to a statement of related appeals and interferences on page 1 of the appeal brief, above the certificate of mailing.

STATUS OF AMENDMENTS AFTER FINAL

The Examiner states that the amendment proposed in the response to final office action mailed on January 21, 2003 has been entered. However, in the advisory action mailed on February 26, 2003 checkboxes 2, 2a, 2c, 7, and 7a are all checked. These boxes all indicate that the amendment was *not* entered.

Applicant assumes that the Examiner has reconsidered the denial of entry made in the advisory action of February 26, and that claim 2 now stands amended as proposed in the response mailed on January 21, 2003.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Irja Zarembok
Typed or Printed Name of Person Signing Certificate

GROUPING OF CLAIMS

The Examiner states that the appeal brief contains no grouping of claims and no statement concerning which claims are to stand or fall together. Applicant draws attention to the grouping of claims at the bottom of page 4.

The requirement of 1.192(*c*)(7) for an explanation of why the claims are believed to be separately patentable is satisfied by statements made in the argument section of the brief. This is consistent with the MPEP 1206, which states that "[t]he reasons may be included in the appropriate portion of the "Argument" section of the brief."[1]

CLAIMS APPEALED

The copy of the claims in the appendix that accompanied the appeal brief does not include the amendment proposed in the response filed January 21, 2003 because the advisory action mailed on February 26, 2003 indicated that those amendments were denied entry.

Since the Examiner now states that the amendment has been entered, Applicant submits a replacement appendix listing claims as they appear with the amendments entered. The only amendment made was that to claim 2. For the Board's convenience, the amendment appears as follows:

> **2. (Twice Amended)** The implant of claim **1**, wherein said pliant membrane forms a balloon having a physical volume, said balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of [~~its~~]said physical volume.

RESPONSE TO EXAMINER

The Examiner's position appears to be that because *Nadol* discloses middle-ear implant balloons generally, it follows that it also discloses balloons having an equivalent volume as specified in the claim. In effect, the Examiner is attempting to argue that disclosure of a genus, namely balloons, amounts to a disclosure of every species within that genus, including species having the equivalent volume recited in the claim.

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[1] *MPEP Eighth edition*, Revision 2, May 2004, page 1200-10.

Applicant submits that the examiner's position is inconsistent with the law. It is well known that a disclosure of a *species* anticipates a claim to a genus.[2] But the converse, that disclosure of a *genus* anticipates a species, is not necessarily true. Were this not the case, the cited *Nadol* patents would preclude patentability of any improvement to a balloon whatsoever.

A succinct statement of this aspect of the law of anticipation is given in *Corning Glassworks v. Sumitomo Electric*,[3] in which an asserted patent claimed germania as a dopant for a core of an optical fiber. The defendant, in an effort to invalidate the asserted claim, drew attention to a publication describing doped cores. This publication neither mentioned, nor specifically excluded cores doped with germania.

The facts described in *Corning* are thus analogous to the case here, in which *Nadol* discloses balloons, but neither mentions, nor specifically excludes balloons having the equivalent volume recited in the claim. The defendant in *Corning*, like the Examiner, attempted to argue that the disclosure of a genus anticipates the species.

The Federal Circuit rejected the defendant's argument, stating that it "approximated one for infringement, rather than inherency, and is confusing at best" and that "under [its] theory, a claim to a genus would inherently disclose all species." The Court went on to state that a publication "is a reference *only* for that which it teaches" [emphasis supplied].

In the similar case of *Minnesota Mining & Manufacturing v. Johnson & Johnson*,[4] the Court stated that "[A]lthough [a patent's] specific claims are subsumed in [a prior art reference's] generalized disclosure...this is not literal identity." In *Minnesota*, the cited references disclosed ranges that were "so broad as to be meaningless" and that provided no guidance on how to construct a product having the patented inventions beneficial properties.

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[2] *In re Slayter*, 276 F.2d 408, 411 (CCPA 1960); *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989).
[3] *Corning Glassworks v. Sumitomo Electric*, 868 F.2d 1251 (Fed. Cir. 1989).
[4] *Minnesota Mining & Manufacturing v. Johnson & Johnson Orthopaedics*, 976, F.2d 1559 (Fed. Cir. 1992).

Again, this is analogous to the case here, in which *Nadol* discloses the *existence* of middle-ear balloons generally, but without even mentioning the concept of equivalent volume that has been found to be so important in making clinically useful middle-ear balloons.

The Federal Circuit has addressed the issue of whether disclosure of a genus anticipates a claim to a species in numerous other cases, though most often in the context of chemical compounds. For example, in the context of a section 103 rejection, the Court has stated that there was *no* rule that "regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."[5] Again, in the context of obviousness, in *In re Baird*[6], the Court stated that "disclosure of millions of compounds does not render obvious a claim to three compounds" and that "the fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious."

Accordingly, Applicant submits that the Examiner's application of the law of anticipation is inconsistent with precedent and that the section 102 rejection of the claims is fundamentally flawed.

No additional fees are believed to be due in connection with the filing of this reply. However, to the extent fees are due, or if a refund is forthcoming, please adjust our deposit account 06-1050, referencing attorney docket "00633-025001."

Respectfully submitted,

Date: October 5, 2004

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[5] *In re Jones*, 874 F.2d 804 (Fed. Cir. 1989), *cert. denied*, 493 U.S. 975 (1989).
[6] *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994)

Appendix of Claims

CLAIMS PENDING ON APPEAL

1. **(Amended)** An implant for implantation in a middle-ear chamber, said implant comprising:

a pliant membrane formed into a balloon, said balloon configured to fit within said middle-ear chamber and to contact an eardrum, said pliant membrane forming a balloon having an equivalent volume selected to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.

2. **(Twice Amended)** The implant of claim 1, wherein said pliant membrane forms a balloon having a physical volume, said balloon having an acoustic impedance corresponding to an equivalent volume of at least 70% of said physical volume.

3. **(Original)** The implant of claim **1**, wherein said implant further comprises a tab extending from an end of said balloon.

4. **(Original)** The implant of claim **3** wherein said tab includes a radio-opaque marker.

5. **(Original)** The implant of claim **1**, wherein said balloon is an ovaloid having a maximum dimension along a principal axis extending between a first end and a second end, and said implant further comprises a tab extending from at least one of said first and second ends.

6. **(Original)** The implant of claim **5**, wherein said balloon is dimensioned to be positioned by surrounding structures within said middle-ear chamber and to displace fluid and soft tissue therefrom, thereby forming a compliant cushion presenting low acoustic impedance to motion of said eardrum.

7. **(Original)** The implant of claim 1, wherein said pliant membrane comprises polymer of vinyledene chloride (PVDC).

8. (Original) The implant of claim **1**, wherein said pliant membrane comprises a biocompatible material.

9. (Original) The implant of claim **8**, wherein said biocompatible material is a polymeric film free of toxic additives.

10. (Original) The implant of claim **8** wherein said pliant membrane is a multilayer membrane and said biocompatible material forms an outermost layer of said multilayer membrane, said outermost layer being exposed, upon implantation of said implant, to the interior of said middle-ear chamber.

11. (Original) The implant of claim **1**, wherein said pliant membrane is substantially impermeable to water, gases and body fluids during protracted contact with body tissues.

12. (Original) The implant of claim **1** wherein said balloon contains at least one naturally occurring gas.

13. (Original) The implant of claim **1** wherein said balloon contains at least one non-naturally occurring gas.

14. (Original) The implant of claim **13**, wherein said non-naturally occurring gas is a large molecular size gas which is non-toxic and to which said pliant membrane is substantially impermeable.

15. (Original) The implant of claim **13**, wherein said non-naturally occurring gas is sulfur hexafluoride.

16. (Original) The implant of claim **1**, wherein said balloon contains a gas mixture at atmospheric pressure.

17. (Original) The implant of claim **1**, wherein said balloon contains a gas mixture having a pressure in the range of approximately 50 mm of water below

atmospheric pressure to approximately 50 mm of water above atmospheric pressure.

18. (Original) The implant of claim **1**, further comprising means for self-inflating said balloon, said self-inflating means including gas at sub-atmospheric pressure effective for self-inflation by diffusion following implantation of said implant into said middle-ear chamber.

19. (Original) The implant of claim **1** further comprising means for initiating self-inflation following implantation, said means for initiating self-inflation including gases at partial pressures effective to initiate self inflation.

20. (Original) The implant of claim **1** wherein said pliant membrane is between approximately 1 mil thick and approximately 4 mils thick.

21. (Amended) An implant for implantation in a middle-ear chamber, said implant comprising:

a plurality of balloons formed from a pliant membrane, said balloons configured to fit within said middle-ear chamber with at least one of said balloons at least partially in contact with the eardrum, each of said balloons having an equivalent volume selected to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound.

22. (Amended) A surgical method for treating middle-ear hearing loss of a patient, said method comprising:

positioning a balloon in the patient's middle ear at least partially in contact with the eardrum, said synthetic balloon being formed of a thin pliant membrane of biocompatible material such that said balloon has an equivalent volume high enough to permit sound-induced motions of the eardrum, ossicles, and the round window membrane to an extent that permits the perception of sound by said patient, said

pliant membrane being substantially impermeable to water and to gases during extended contact with body tissues.

23. (**Original**) A surgical method according to claim **22**, wherein positioning a balloon includes positioning the balloon between the eardrum and the bone covering the cochlea.

24. (**Original**) A surgical method according to claim **22**, further comprising exposing the patient's middle ear by elevating a tympano-meatal flap before disposing said balloon in the middle ear.

25. (**Original**) The surgical method of claim **24**, further comprising securing said balloon into position with an anchor formed of resorbable packing.

26. (**Original**) The surgical method of claim **22**, further comprising positioning one or more additional balloons in the patient's middle-ear such that said additional balloons are mechanically coupled to said balloon.